

What is claimed is:

- 10015538-121301
1. A process for the preparation of a agglomerated solid dosage form, comprising
- (1) preparing an aqueous slurry of
 - (a) microcrystalline cellulose;
 - (b) a microcrystalline cellulose compressibility augmenting agent which
 - (i) physically restricts the proximity of the interface between adjacent cellulose surfaces;
 - (ii) inhibits interactions between adjacent cellulose surfaces, for example, via the creation of a hydrophobic boundary at cellulose surfaces; or
 - (iii) accomplishes both (i) and (ii) above; and
 - (c) an active agent;
 - (2) thereafter drying the resultant aqueous slurry in a manner which inhibits quasi-hornification, thereby obtaining an agglomerated material which is directly compressible into a solid dosage form.
2. A process of claim 1, comprising utilizing a spray drying technique to dry the aqueous slurry.
3. A process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB of at least about 10.
4. A process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB of at least about 15.
5. A process of claim 1, wherein said compressibility augmenting agent is a surfactant having an HLB from about 15 to about 40.

6. A process of claim 5, wherein said compressiblility augmenting agent is sodium lauryl sulfate.

7. A process of claim 5, wherein said compressiblility augmenting agent is a polysorbate.

8. A process of claim 1, wherein said compressiblility augmenting agent is a silicon dioxide portion of said agglomerate being derived from a silicon dioxide having an average primary particle size from about 1 nm to about 100 μ m.

9. A process of claim 8, wherein said silicon dioxide is included in amount from about 0.1% to about 20% by weight, based on the weight of microcrystalline cellulose.

10. A process of claim 3, wherein said surfactant is included in amount from about 0.1% to about 20% by weight, based on the weight of microcrystalline cellulose.

11. A process of claim 9, wherein said silicon dioxide is colloidal silicon dioxide.

12. A process of claim 1, further comprising adding a sustained release carrier into the aqueous slurry, and drying the aqueous slurry in such a manner as to obtain agglomerated sustained release particles.

13. A process of claim 12, wherein said sustained release carrier is selected from the group consisting of an alkyl cellulose, an acrylic polymer or copolymer, a cellulose ether, a cellulose ester, and mixtures thereof.

14. The process of claim 12, wherein said sustained release carrier is selected from natural or a synthetic gums.

Pub
cont

15. A process of claim 1, further comprising adding a film forming agent into the aqueous slurry, and drying the aqueous slurry in such a manner as to obtain agglomerated particles having a film coating.

16. A process of claim 1, further comprising compressing the resultant granulate into tablets.

17. A process of claim 12, further comprising compressing the resultant granulate into tablets.

Pub
cont

18. A process of claim 15, further comprising compressing the resultant granulate into tablets.

19. A process according to claim 1, wherein the solids content of the aqueous slurry is from about 0.5 to about 25%, by weight.

20. A process according to claim 1, wherein the solids content of the aqueous slurry is from about 15 to about 20%, by weight.

21. A process according to claim 12, wherein the solids content of the aqueous slurry is from about 0.5 to about 25%, by weight.

22. A process according to claim 12, wherein the solids content of the aqueous slurry is from about 15 to about 20%, by weight.

23. A process according to claim 15, wherein the solids content of the aqueous slurry is from about 0.5 to about 25%, by weight.

24. A process according to claim 15, wherein the solids content of the aqueous slurry is from about 15 to about 20%, by weight.

25. A product according to claim 1.

26. A product according to claim 12.

27. A product according to claim 15.

28. A process of claim 12, wherein a further amount of sustain release carrier is admixed with said agglomerated sustain release particles and the resulting mixture is compressed into tablets.

29. A process of claim 28, wherein said mixture is prepared via wet granulation.

30. A process of claim 28, wherein a further amount of active ingredient is also added.

31. A process of claim 12 further comprising compressing said agglomerated sustain release particles into a tablet, and further applying an additional portion of said sustain release carrier as a coating onto said tablet.

10015538-121301

add
B2